REMARKS

Rejection of Claims Under 35 U.S.C. 102

Claims 1-4 and 31 stand rejected under 35 U.S.C. 102 for allegedly being anticipated by U.S. Patent No. 6,406,498 to Tormala (the '498 patent). Applicants traverse this rejection. Claim 1 recites a multifunctional synthetic bioabsorbable device comprising solid particles of a pharmacological agent. The Examiner states that according to U.S. Patent No. 6,579,533, bioactive glass is anti-bacterial and thus the bioactive glass is considered a pharmaceutical agent. Bioactive glasses belong to a group of bioceramics that are used as biomaterials (See Exhibit A). Although some bioactive glasses have anti-bacterial properties, they are not considered "pharmacological agents" as that term is understood by one in the art. "Pharmacological" is an adjective derived from the word "pharmacology," which according to the New Oxford Dictionary of English (Clarendon Press, Oxford 1998) is "the branch of medicine concerned with the uses, effects and modes of action of drugs." (See Exhibit B). Bioactive glasses are biomaterials not drugs. As such, a bioactive glass is not a "pharmacological agent" as recited in claim 1. Accordingly, Applicants submit that claim 1 (and all claims that depend therefrom) are not anticipated by the '498 patent and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 103

Claims 1-26 and 31 stand rejected as being allegedly rendered obvious by EP 1157708 to Fischer ("Fischer") in view of the '498 patent. Fischer states that antimicrobial agents should not undergo chemical degradation or modification, or loss of anti-microbial properties under processing conditions. (See e.g. page 3, lines 22-24). However, there is no teaching or suggestion that the a pharmacological agent should retain its solid particulate form in the melt-processing of the matrix as recited in claim 1. Therefore, it would not be obvious to produce a multi-functional bioabsorbable device which comprises a pharmaceutical agent and cavities around the solid particles of the pharmaceutical agent dispersed in a synthetic bioabsorbable oriented polymer matrix as recited by claim 1. Accordingly, Applicants submit that claim 1 (and all claims that depend therefrom) are not rendered obvious by the combination of the '498 patent and Fischer and Applicants request withdrawal of this rejection.

PATENT

Application No. 10/565,023 Attorney Docket: 12808/29

Conclusion

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees that are required in connection with the filing of this response are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

Respectfully submitted,

Dated: March 3, 2010 /Zeba Ali/

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Bioceramics

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Ceramics used for the repair and reconstruction of diseased or damaged parts of the musculo-skeletal system, termed bioceramics, may be bioinert (e.g., alumina and zirconia), resorbable (e.g., tricalcium phosphate), bioactive (e.g., hydroxyapatite, bioactive glasses, and glass-ceramics), or porous for tissue ingrowth (e.g., hydroxyapatite-coated metals). Applications include replacements for hips, knees, teeth, tendons, and ligaments and repair for periodontal disease, maxillofacial reconstruction, augmentation and stabilization of the jaw bone, spinal fusion, and bone repair after tumor surgery. Pyrolytic carbon coatings are thromboresistant and are used for prosthetic heart valves. The mechanisms of tissue bonding to bioactive ceramics have resulted in the molecular design of bioceramics for interfacial bonding with hard and soft tissue. Bioactive composites are being developed with high toughness and elastic modulus that match with bone. Therapeutic treatment of cancer has been achieved by localized delivery of radioactive isotopes via glass beads. Clinical success of bioceramics has led to a remarkable advance in the quality of life for millions of people.

I. Introduction

Many millennia ago, the discovery that fire would irrevers-ibly transform clay into ceramic pottery led to an agrarian society and an enormous improvement in the quality and length of life. Another revolution has occurred in the use of ceramics during the past four decades to improve the quality of life. This revolution is the innovative use of specially designed ceramics for the repair, reconstruction, and replacement of diseased or damaged parts of the body. Ceramics used for this purpose are termed "bioceramics." Bioceramics can be polycrystalline (alumina or hydroxyapatite), bioactive glass, bioactive

glass-ceramic (A/W), or bioactive composite (polyethylenehydroxyapatite)

Many specialty ceramics and glasses have been developed during this century for use in the health care industry, e.g., eveglasses, diagnostic instruments, chemical ware, thermometers, tissue culture flasks, fiber optics for endoscopy, and carriers for enzymes and antibodies.1 Ceramics also are used widely in dentistry as restorative materials, gold porcelain crowns, glass-filled ionomer cements, dentures, etc. The materials used in these applications are called dental ceramics.2

This review is devoted to the use of bioceramics as implants to repair parts of the body, usually the hard tissues of the musculo-skeletal system, such as bones, joints, or teeth, although use of carbon coatings for replacement of heart valves also is included. Many ceramic compositions have been tested for use in the body, 1.3 however, few have achieved human clinical application. Clinical success requires the simultaneous achievement of a stable interface with connective tissue and a match of the mechanical behavior of the implant with the tissue to be replaced. Only the few bioceramics that meet these severe requirements for clinical success are emphasized in this review. Historical developments of bioceramics have been presented by Hulbert et al.

(1) Need for Bioceramics

Bioceramics are needed to alleviate pain and restore function to diseased or damaged parts of the body. A major contributor to the need for "spare parts" for the body is the progressive deterioration of tissue with age. Bone is especially vulnerable to fracture in older people because of a loss of bone density and strength with age.4 Figure 1 summarizes the effect of time on bone strength and density from the age of 30 years onward. The effect is especially severe in women because of hormonal changes associated with menopause. Bone density decreases because bone-growing cells (osteoblasts) become progressively less productive in making new bone and repairing microfractures. The lower density greatly deteriorates the strength of the porous bone, called trabecular or cancellous bone (Fig. 2), in the ends of long bones and in vertebrae. An unfortunate consequence is that many old people fracture their hips or have collapsed vertebrae and spinal problems.

The great challenge facing the use of ceramics in the body is to replace old, deteriorating bone with a material that can func-

P. W. Brown-contributing editor

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EXHIBIT B

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DERIVATIVES Phorizolo [farrisenk] adjective,
 Phorizology [farrisenk] farrisen, plants of the farrisen of the farrisen

 ORIGIN Old English fariress, via ecclesiastical Latin from Greek Phartistos, from Aramaic prisapyst 'separated ones' (related to Hebrew phrisi 'separated').

pharmacautical /forms'sjuttk(s); > sejective of or relating to medicinal drugs, or their preparation, use, or sale.

manufactured for use as a medicinal drug.

s(pharmacouticals) shares in companies manufacturing medicinal drug.

DERIVATIVES pharmacoutically afterb, pharmacoutica joint noun.
 ORIGIN mid 17th cent: via late Latin from Greek

 ORIGIN mid 17th cent.: via late Latin from Greek pharmakeutikes (from pharmakeutis 'druggist', from pharmakon 'drug') + -al.

pharmacist > new a person who is professionally qualified to prepare and dispense medicinal drugs. pharmaco- formskup > nembing from relating to drugs: pharmacogenetic.

Obtain from Greek pharmakon 'drug, medicine'.

pharmacodynamics > pleast nous [rested as sing] the branch of pharmacology concerned with the effects of drugs and the mechanism of their action.

- DERIVATIVES pharmacodynamic edjective.

pharmacogenetics > plural seus (tested as sing)
the branch of pharmacology concerned with the
effect of genetic factors on reactions to drugs.

pharmacognosy [fo.mo'kognosif > sees [mass news] the branch of knowledge concerned with medicinal drugs obtained from plants or other natural sources.

DERIVATIVES pharmacognosist noun.
 ORIGIN mid 19th cent.: from pharmaco-'of drugs'
 gnösis 'knowledge'.

pharmacokinetics > plant nous (mass) as sing) the branch of pharmacology concerned with the movement of drugs within the body.

No. of Contract of

DERIVATIVES pharmacokinetic afactive.
 pharmacology > sees [seat note] the branch of medicine concerned with the uses, effects, and modes of action of drugs.

- DERIVATIVES pharmacologic adjectes, pharmacological adjective, pharmacologically adverts, pharmacologist nous. - ORIGIN early 18th cent: from modern Latin

pharmacologia, from Greek pharmakon 'drug',
pharmacopoela /,fo.mska'pi.a/ (US also
pharmacopoels) seen a book, especially an official
publication, containing a list of medicinal drugs
with their effects and directions for their use.

ma stock of medicinal drugs.

onigin early 17th cent.: modern Latin, from Greek
pharmakopoits 'art of preparing drugs', based on

pharmakon 'drug' + -protes 'making'.

pharmacotherapy > noun [mass noun] medical treatment by means of drugs.

pharmacy > sees (st. -less) a shop or hospital dispensary where medicinal drugs are provided or sold.

Biross acm) the science or practice of the preparation and dispensing of medicinal drugs.

ORIGIN late Middle English (denoting the administration of drugs) from Old French fermack,

administration of drugs) from Old French farmacie, via medieval Latin from Greek pharmakeis 'practice of the druggist', based on pharmakon 'drug'. Pharos fieros a lighthouse, often considered one of the Seven Wonders of the World, erected by

Prolemy II (308-246 sc) in c.280 sc on the island of Pharos, off the coast of Alexandria.

eter room a pharee a lighthouse or a beacon to guide sailors.

pharyngesi fo'rm(d)yxl, farm'dyixl > aspective of or relating to the pharynx.

of trianing for a speech sound) produced by articulating the root of the toague with the pharyux, a feature of certain consonants in Arabic, for example.

> 2000 Promits a pharyugeal consonant.

- ORIGIN early 19th cent.: from modern Latin

pharyngeus (from Greek pharuns, pharung- 'throat') +

pharyngoalize |form(d)palaz| (also -tee) | > web | |with obj. | Phonoics articulate (a speech sound) with constriction of the pharynx.

~ DERIVATIVES | pharyngoalization noun.

pharyngitis / farm 'dyanta/ > soun [mas soun] Medicine inflammation of the pharynx, causing a sore throat.

pharysego- #5'rmgoo/ > combining form of or relating to the pharyux: pharyagotomy.

ORIGIN from modern Latin pharyux, pharyng.

pharyngotomy / fam gotomi > nous (pl. -tes) a surgical incision into the pharynx.

phasynx | flamks| > non (pl. phasynges | f-mid(pix)| Animy & losopy the membrane-lined cavity behind the nose and mouth, connecting

them to the oesophagus.

#Zooky the part of the alimentary canal immediately behind the mouth in invertebrates.

ORIGIN late 17th cent; modern Latin from Greek

- ORIGIN late 17th cent.: modern Latin, from Greek phorous, phorong.

phasocogale [fa/skngsh] been a small arboreal flesh and nectar-eating Australian marsupial with a pointed snout, large eyes and ears, and a bushy tall.

Gience Phasocogale, family Designative, then species.

ORIGIN modern Latin, from Greek plankiller 'purse'
 + gold 'weasel'.

 Resource forth pages 4 - distinct period on store in a

phase for: | > sees 1 a distinct period or stage in a process of change or forming part of something's development: the final phases of the war | (as mostles) phase two of the development is in progress.

as stage in a person's psychological development of especially a period of temporary unhappiness or difficulty during adolescence or a particular stage during childhood most of your four are going themselving phase, seach of the aspects of the moon or a planet, according to the amount of its illustriation, according to the amount of its illustriation, and the list quarter, a each of the separate versus in an eventing competition.

2 Zooby a genetic or seasonal variety of an animal's coloration.

se stage in the life cycle or annual cycle of an animal.

3 Chrostoy a distinct and homogeneous form of matter (i.e. a particular solid, liquid, or gas) separated by its surface from other forms.

4 Physic the relationship in time between the successive states or cycles of an oxillatine or.

successive states or cycles of an oscillating or repeating system (such as an alternating electric current or a light or sound wave) and either a fixed reference point or the states or cycles of another system with which it may or may not be in system with which it may or may not be

synchrony, aseach of the electrical windings or connections of a polyphase machine or circuit. 5 Liegolics (in systemic grammar) the relationship between a catentitiv event and the very that follows

it, as in she hoped to succeed and I like swimming.

as structure containing two wrbs in such a
relationship.

were [with oit,] (usu. he phaned) 1 carry out isomething) in gradual stages: the work is bring phaned over a number of years [its sit, phaned] a phaned withdrawed of troops: siphene consetting intensity introduce into (or withdraw from) use in gradual stages; our armed

withdraw from) use in gradual stages: our armed forcet pokey uses to be phased in our please. 2 Physics adjust the phase of (something), especially so as to synchronize it with something eise.

SO SO SYNCHOLDS IT WAS SOMETHING SINCE THEASES IN (or out off) phease being or happening in (or out off) synchrony or harmony; the cabling work should be carried out its please with the building work.

- DEIGH early 19th cent (denoting each aspect of the moon): from Freach phase, based on Greek phase's appearance', from the base of phases to show'.
phase angle > west Physic an angle representing a

difference in phase, 360 degrees (2π radians) corresponding to one complete cycle.

**whitemore the angle between the lines joining a given

account the angle between the lines joining a given planet to the sun and to the earth.
shase contrast a sees [ness row] the technique

in microscopy of introducing a phase difference between parts of the light supplied by the condenser so as to enhance the outlines of the sample, or the boundaries between parts differing in optical density. phase diagram > new Changry representing the limits of stability of the phases in a chemical system at equilibries respect to variables such as composite temperature.

phase-lock b web [wh cti] Batton frequency of (an oscillator or a laser) rela stable oscillator of lower frequency by that utilizes a correction signal derived phase difference required.

stable oscillator of lower frequency by a that utilizes a correction signal derived of phase difference generated by any third frequency.

phase modulation > 1844 [7255 1926]

variation of the phase of a radio or other means of carrying information such of an signal. phaser > soun 1 an instrument that alternational by phasing it.

signal by phasing it.

2 (in science fiction) a weapon that delivers that can stun or annihilate.

phase rule > nous Chambiry a rule reason possible numbers of phases, constrained degrees of freedom in a chemical system phase shift > nous Payers a change in the pa

phase space > sees Phons a multidium space in which each axis corresponds to cocoordinates required to specify the storphysical system, all the coordinates local represented so that a point in the corresponds to a state of the system.

phase velocity > nous Physics the open propagation of a sine wave or a true component of a complex wave, equal to product of its wavelength and frequency.

phase / femile > edjective of or relating to a or phases or phase or phases or phase or phas

newsy Physicagy characterized by occurrence is rather than continuously: phase and more reflexe.

phasing a seen (mass news) the relationship is the timing of two or more event.

the timing of two or more event; adjustment of this relationship grapher is were used to furnishing the planting of profit to the modification of the sound signal from an guitar or other electronic instrument by his phase shift into either of two copies of it as

a phase shift into either of two copies of it ass recombining them. a the action of dividing a task or process into several stages: the photogseveral project.

Phasmida / fazunda/ 1 Estanology an order of a

that comprises the stick insects and leaf as They have very long bodies that resemble to leaves. 2 Indeed a class of nematodes that includes parasific hookworms and roundworms. Asset

SECREMENTEA.

- DERIVATIVES phasemed soun & adjective.

- ORIGIN modern Latin (plural), from latin secretary.

-oxigin modern Latin (plural), from lans
'apparition', from Greek.

phasor / fezzi > neur Physic a line issed to my
a complex electrical quantity as a vector.

- ORIGIN 1940s: from PHASE, on the patterned phast flat | = adjective back stang excellent a lower with a really phat flank sound.

- ORIGIN 1970s (originally used to describe a second

on the sense 'sexy, attractive'; of uncertain so in the sense 'sexy, attractive'; of uncertain so phastic !'fatik' is adjective denoting or results language used for general purposes of sense.

interaction, rather than to convey informed atk questions. Utterances such as helic how and and not morning that it? are phatic. ORIGIN 1920s: from Greek phatos species phatiks 'affirming'.

- ORIGIN 1920s: from Greek phates 'spo phatites 'affirming'. PhD > abtreviation for Doctor of Philosophy

 OBIGIN from Latin philosophiae doctor.
 pheasant > som a large long-tailed gar native to Asia, the male of which typically a showy plumage.
 Family Phasiandae, several genero and many sext

particular the common phenesant (Phenhous of which has been widely infloation for shocking. — oktoth Middle English: from Old French, Latin from Greek phensions (bird) of name of a river in the Caucasus, from bird is said to have spread westwards.

pheasantry ➤ nose (g. -les) a place pheasants are reared or kept. pheasant's eye ➤ nose a plant of the best

b But | d dog | flew | g get | in he | j yes | k cat | l log | m mean | n no | p pen | r red | s at | t top | v voice | w we | z zoo | f ahe | g decision | 8 thin | 8 this | ŋ nog | x lock | 0 decision |